986/85/664

NEWARK PUBLIC LIBRARY

(Slip Opinion)

JUL 16 1986

GOVT PUBS.

DEPOSITORY 376

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

YOUNG, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION *v.* COMMUNITY NUTRITION INSTITUTE ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 85–664. Argued April 30, 1986—Decided June 17, 1986

The Federal Food, Drug, and Cosmetic Act (Act) provides in 21 U. S. C. § 346 that when the addition of any poisonous or deleterious substance to food is required in the production thereof or cannot be avoided by good manufacturing practice, the Secretary of Health and Human Services "shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." The Food and Drug Administration (FDA), the Secretary's designee for enforcing the Act, has long interpreted the phrase beginning "to such extent" to modify the word "shall" rather than "the quantity therein or thereon," and therefore views the decision whether to promulgate a § 346 regulation (tolerance level) as a determination to be made by the FDA. Rather than setting a tolerance level for aflatoxin, a potent carcinogen that is unavoidably present in some foods, the FDA set an action level of 20 parts per billion (ppb) (an action level assures food producers that the FDA ordinarily will not enforce the Act's general adulteration provisions against them if the quantity of the harmful substance in food is less than a specified quantity). But in 1980, the FDA published a notice in the Federal Register that the Act would not be enforced as to a certain harvest of corn to be used for livestock and poultry feed where it contained no more than 100 ppb. Respondents, two public-interest groups and a consumer, brought suit against petitioner Commissioner of Food and Drugs in Federal District Court, alleging that the Act requires the FDA to set a tolerance level for aflatoxin before allowing the shipment of food containing the substance, that in this case the FDA had employed insufficient procedures to set the aflatoxin action level even if a tolerance level was not required, and that the FDA's deci-

JU 6.8/b:

READEX FICHE best copy available

Syllabus

sion to grant the exemption from the action level violated the Act and the FDA's own regulations. Adopting the FDA's longstanding interpretation of § 346 as giving it discretion whether to promulgate a tolerance level, the District Court, on a motion for summary judgment, ruled that the FDA need not establish a tolerance level for aflatoxin before allowing the shipment of the alfatoxin-tainted corn. The Court of Appeals reversed, holding that the FDA's interpretation of § 346 conflicted with its plain language.

Held: In light of § 346's inherent ambiguity, the FDA's interpretation of the provision is sufficiently rational to preclude a court from substituting its judgment for that of the FDA. The legislative history is equally ambiguous and provides no support for assertions that the FDA's interpretation is insufficiently rational to warrant this Court's deference. Pp. 5–9.

244 U. S. App. D. C. 279, 757 F. 2d 354, reversed and remanded.

O'CONNOR, J., delivered the opinion of the Court, in which BURGER, C. J., and BRENNAN, WHITE, MARSHALL, BLACKMUN, POWELL, and REHNQUIST, JJ., joined. STEVENS, J., filed a dissenting opinion.

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 85-664

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION, PETITIONER *v.* COMMUNITY NUTRITION INSTITUTE ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

[June 17, 1986]

JUSTICE O'CONNOR delivered the opinion of the Court.

We granted certiorari in this case to determine whether the Court of Appeals for the District of Columbia Circuit correctly concluded that the Food and Drug Administration's longstanding interpretation of 21 U. S. C. §346 was in conflict with the plain language of that provision. 474 U. S. —— (1985). We hold that, in light of the inherent ambiguity of the statutory provision and the reasonableness of the Food and Drug Administration's interpretation thereof, the Court of Appeals erred. We therefore reverse.

I

A

The Food and Drug Administration (FDA) enforces the Federal Food, Drug, and Cosmetic Act (Act) as the designee of the Secretary of Health and Human Services. 21 U. S. C. §371(a). See also 21 CFR §5.10. The Act seeks to ensure the purity of the Nation's food supply, and accordingly bans "adulterated" food from interstate commerce. 21 U. S. C. §331(a). Section 342(a) deems food to be "adulterated"

> "(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food

> shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than [exceptions not relevant here]) which is unsafe within the meaning of section 346a(a) of this title . . . ." 21 U. S. C. § 342(a).

As this provision makes clear, food containing a poisonous or deleterious substance in a quantity that ordinarily renders the food injurious to health is adulterated. If the harmful substance in the food is an added substance, then the food is deemed adulterated, even without direct proof that the food may be injurious to health, if the added substance is "unsafe" under 21 U. S. C. § 346.

Section 346 states:

> "Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect . . . food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated . . . ."

Any quantity of added poisonous or added deleterious substances is therefore "unsafe," *unless* the substance is required in food production or cannot be avoided by good manufacturing practice. For these latter substances, "the Secretary shall promulgate regulations limiting the quantity

therein or thereon to such extent as he finds necessary for the protection of public health." It is this provision that is the heart of the dispute in this case.

The parties do not dispute that, since the enactment of the Act in 1938, the FDA has interpreted this provision to give it the discretion to decide whether to promulgate a § 346 regulation, which is known in the administrative vernacular as a "tolerance level." Tolerance levels are set through a fairly elaborate process, similar to formal rulemaking, with evidentiary hearings. See 21 U. S. C. § 371(e). On some occasions, the FDA has instead set "action levels" through a less formal process. In setting an action level, the FDA essentially assures food producers that it ordinarily will not enforce the general adulteration provisions of the Act against them if the quantity of the harmful added substance in their food is less than the quantity specified by the action level.

B

The substance at issue in this case is aflatoxin, a bacterial mold that grows in some foods. Aflatoxin, a potent carcinogen, is indisputedly "poisonous" or "deleterious" under §§ 342 and 346. The parties also agree that, although aflatoxin is naturally and unavoidably present in some foods, it is to be treated as "added" to food under § 346. As a "poisonous or deleterious substance added to any food," then, aflatoxin is a substance falling under the aegis of § 346, and therefore is at least potentially the subject of a tolerance level.

The FDA has not, however, set a § 346 tolerance level for aflatoxin. It has instead established an action level for aflatoxin of 20 parts per billion (ppb). In 1980, however, the FDA stated in a notice published in the *Federal Register*:

> "The agency has determined that it will not recommend regulatory action for violation of the Federal Food, Drug, and Cosmetic Act with respect to the interstate shipment of corn from the 1980 crop harvested in North Carolina, South Carolina, and Virginia and which con-

> tains no more than 100 ppb aflatoxin . . . ." 46 Fed. Reg. 7448 (1981).

The notice further specified that such corn was to be used only as as feed for mature, nonlactating livestock and mature poultry. *Id.*, at 7447.

In connection with this notice, two public-interest groups and a consumer (respondents here) brought suit against the Commissioner of Food and Drugs (petitioner here) in the United States District Court for the District of Columbia. Respondents alleged that the Act requires the FDA to set a tolerance level for aflatoxin before allowing the shipment in interstate commerce of food containing aflatoxin; that the FDA had employed insufficiently elaborate procedures to set its aflatoxin action level even if a tolerance level was not required; and that the FDA's decision to grant the 1980 exemption from the action level independently violated the Act and the FDA's own regulations.

On a motion for summary judgment, the District Court deferred to the FDA's interpretation of § 346, and therefore ruled that the FDA need not establish a tolerance level for aflatoxin before allowing the shipment of aflatoxin-tainted corn in interstate commerce. The District Court also ruled against respondents on their other claims.

The Court of Appeals reversed the District Court's conclusion as to the proper interpretation of § 346. 244 U. S. App. D. C. 279, 757 F. 2d 354 (1985). The Court of Appeals determined that Congress had spoken directly and unambiguously to the precise question at issue:

> "The presence of the critical word 'shall' plainly suggests a directive to the Secretary to establish a tolerance, if a food with an unavoidable . . . deleterious substance is to be considered unadulterated.
>
> . . . . .
>
> It is . . . clear from the structure of the sentence at issue here that the phrase relied upon by the Secretary

> simply does not modify the pivotal word 'shall.'" *Id.*, at 282, 283, 757 F. 2d, at 357, 358.

After examining the entirety of § 346, the Court of Appeals also concluded that, since tolerance levels make food with added harmful substances unadulterated, tolerance levels were necessary before food could be judged unadulterated. *Id.*, at 283, 757 F. 2d, at 358.

The Court of Appeals considered none of the other issues before the District Court, and therefore only the § 346 issue is before this Court.

II

The FDA's longstanding interpretation of the statute that it administers is that the phrase "to such extent as he finds necessary for the protection of public health" in § 346 modifies the word "shall." The FDA therefore interprets the statute to state that the FDA shall promulgate regulations to the extent that it believes the regulations necessary to protect the public health. Whether regulations are necessary to protect the public health is, under this interpretation, a determination to be made by the FDA.

Respondents, in contrast, argue that the phrase "to such extent" modifies the phrase "the quantity therein or thereon" in § 346, not the word "shall." Since respondents therefore view the word "shall" as unqualified, they interpret § 346 to require the promulgation of tolerance levels for added, but unavoidable, harmful substances. The FDA under this interpretation of § 346 has discretion in setting the particular tolerance level, but not in deciding whether to set a tolerance level at all.

Our analysis must begin with *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837 (1984). We there stated:

> "First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter,

> for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute. . . . [A] court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Id.*, at 842–844.

While we agree with the Court of Appeals that Congress in § 346 was speaking directly to the precise question at issue in this case, we cannot agree with the Court of Appeals that Congress unambiguously expressed its intent through its choice of statutory language. The Court of Appeals' reading of the statute may seem to some to be the more natural interpretation, but the phrasing of § 346 admits of either respondents' or petitioner's reading of the statute. As enemies of the dangling participle well know, the English language does not always force a writer to specify which of two possible objects is the one to which a modifying phrase relates. A Congress more precise or more prescient than the one that enacted § 346 might, if it wished petitioner's position to prevail, have placed "to such extent as he finds necessary for the protection of public health" as an appositive phrase immediately after "shall" rather than as a free-floating phrase after "the quantity therein or thereon." A Congress equally fastidious and foresighted, but intending respondents' position to prevail, might have substituted the phrase "to the quantity" for the phrase "to such extent as." But the Congress that actually enacted § 346 took neither tack. In the absence of such improvements, the wording of § 346 must remain ambiguous.

The FDA has therefore advanced an interpretation of an ambiguous statutory provision.

> "This view of the agency charged with administering the statute is entitled to considerable deference; and to sustain it, we need not find that it is the only permissible construction that [the agency] might have adopted but only that [the agency's] understanding of this very 'complex statute' is a sufficiently rational one to preclude a court from substituting its judgment for that of [the agency]. *Train, Inc.* v. *NRDC*, 421 U. S. 60, 75, 87 (1975) . . . ." *Chemical Manufacturers Assn.* v. *Natural Resources Defense Council*, 470 U. S. ——, —— (1985) (slip op. 8–9).

We find the FDA's interpretation of § 346 to be sufficiently rational to preclude a court from substituting its judgment for that of the FDA.

To read § 346 as does the FDA is hardly to endorse an absurd result. Like any other administrative agency, the FDA has been delegated broad discretion by Congress in any number of areas. To interpret Congress' statutory language to give the FDA discretion to decide whether tolerance levels are necessary to protect the public health is therefore sensible.

Nor does any other portion of § 346 prohibit the FDA from allowing the shipment of aflatoxin-tainted food without a tolerance level, despite the Court of Appeals' conclusion to the contrary. The Court of Appeals stated:

> "Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." 244 U. S. App. D. C., at 283, 757 F. 2d, at 358.

The premise of the Court of Appeals is of course correct: the Act does provide that when a tolerance level has been set and

a food contains an added harmful substance in a quantity below the tolerance level, the food is legally not adulterated. But one cannot logically draw from this premise, or from the Act, the Court of Appeals' conclusion that food containing substances *not* subject to a tolerance level *must be* deemed adulterated. The presence of a certain premise (*i. e.*, tolerance levels) may imply the absence of a particular conclusion (*i. e.*, adulteration) without the absence of the premise implying the presence of the conclusion. For example, the presence of independent and adequate state-law grounds in the decision of a state supreme court means this Court has no jurisdiction over the case, but the absence of independent and adequate state grounds does not mean that this Court necessarily has jurisdiction. The Act is silent on what specifically to do about food containing an unavoidable, harmful, added substance for which there is no tolerance level; we must therefore assume that Congress intended the general provisions of § 342(a) to apply in such a case. Section 342(a) remains available to the FDA to prevent the shipment of any food "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health." See generally *United States* v. *Lexington Mill & Elevator Co.*, 232 U. S. 399, 411 (1914) (discussing proper interpretation of the language that became § 342(a)).

The legislative history of the Act provides no single view about whether Congress intended § 346 to be mandatory or permissive with respect to tolerance levels. Compare, *e. g.*, Confidential House Committee Print 2, on Interstate and Foreign Commerce, 75th Cong., 1st Sess., S. 5, § 406(a), reprinted in 5 Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments 767, 792 (Dept. of Health, Education, and Welfare 1979) (changing, without explanation, words "is authorized to" to "shall" in relevant provision) with H. R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (1938) (stating that, under the Act, "the establishment of tolerances is *authorized*") (emphasis added). A clearer indi-

cation of Congress' intentions with regard to tolerance levels occurred in 1954, when Congress condemned the cumbersomeness of the tolerance-level procedure as applied to pesticides. Congress fashioned a more streamlined procedure for those and other deliberately added substances. See 21 U. S. C. §346a. But in revisiting §346, Congress did *not* change the procedures governing unintentionally added substances like aflatoxin. This failure to change the scheme under which the FDA operated is significant, for a "congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *NLRB* v. *Bell Aerospace, Co.*, 416 U. S. 267, 275 (1974). See *FDIC* v. *Philadelphia Gear Corp.*, 476 U. S. ——, —— (1986); *Zenith Radio Corp.* v. *United States*, 437 U. S. 443, 457 (1978). In sum, although the legislative history is not unambiguous, it certainly is no support for assertions that the FDA's interpretation of §346 is insufficiently rational to warrant our deference.

Finally, we note that our interpretation of §346 does not render that provision superfluous, even in light of Congress's decision to authorize the FDA to "promulgate regulations for the efficient enforcement of [the] Act." 21 U. S. C. §371(a). Section 346 gives the FDA the authority to choose whatever tolerance level is deemed "necessary for the protection of public health," and food containing a quantity of a required or unavoidable substance less than the tolerance level "shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated." Section 346 thereby creates a specific exception to §342(a)'s general definition of adulterated food as that containing a quantity of a substance that renders the food "ordinarily . . . injurious to health." Simply because the FDA is given the choice between employing the standard of §346 and the standard of §342(a) does not render §346 superfluous.

For the reasons set forth, the judgment is reversed and the case remanded to the Court of Appeals for the District of Columbia for further proceedings consistent with this opinion.

Reversed.

SUPREME COURT OF THE UNITED STATES

No. 85-664

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION, PETITIONER *v.* COMMUNITY NUTRITION INSTITUTE ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

[June 17, 1986]

JUSTICE STEVENS, dissenting.

The parties agree that aflatoxins are added, unavoidable contaminants of food and as such are governed by the following provision of the Federal Food, Drug, and Cosmetic Act:

> "[W]hen such substance . . . cannot be so avoided, the Secretary *shall promulgate regulations* limiting the quantity therein or thereon *to such extent* as he finds necessary for the protection of public health, and any quantity exceeding the limits *so fixed* shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title." 21 U. S. C. §346 (emphasis added).

To one versed in the English language, the meaning of this provision is readily apparent. The plain language of the section tells us when the Secretary's duty to promulgate regulations arises—"when such substance . . . cannot be so avoided"; it tells us the purpose of the regulations—to establish a tolerance level that will enable manufacturers to know what they can lawfully produce and to enable the public to know what they can safely consume; and it tells us what standard he should employ in drafting them—"to such extent as he finds necessary for the protection of public health." For purposes of deciding this case, the parties' agreement

that aflatoxins are substances that "cannot be so avoided" within the meaning of the section triggers the obligation to initiate rulemaking.

The Court's contrary conclusion reflects an absence of judgment and of judging. Before exploring either infirmity, it is worthwhile to summarize the Court's reason for reading the section to authorize, but not require, the promulgation of regulations. First, the Court declares that the qualifying language—"to such extent as he finds necessary for protection of the public health"—is a "dangling participle" that might or might not modify the words "shall promulgate regulations." *Ante*, at 6. Second, as between the two readings of this "ambiguous statutory provision," *ante*, at 7, deference dictates that the Commissioner of Food and Drugs (to whom enforcement of the Act has been delegated) may take his pick.

The Court's finding of ambiguity is simply untenable. The antecedent of the qualifying language is quite clearly the phrase "limiting the quantity therein or thereon," which immediately precedes it, rather than the word "shall," which appears eight words before it. Thus, the Commissioner is to "limi[t] the quantity [of an added, unavoidable poisonous or deleterious substance] therein or thereon to such extent as he finds necessary for the protection of public health."[1] By instead reading the section to mean that "the Secretary shall

---

[1] This interpretation is in accord with the Committee Report on the House Bill, which became the Food, Drug, and Cosmetic Act of 1938. The Report states that "[t]he addition of poison to foods is prohibited except where such addition is necessary or cannot be avoided; and in such cases tolerances *are* provided limiting the amount of added poison to the extent necessary to safeguard the public health." H. R. Rep. No. 2139, 75th Cong., 3d Sess., pt. 1, p. 2 (1938) (emphasis added). By using the present tense, the Report makes clear that the qualifying language is operative when regulations *are* promulgated—to limit the amount of poison "to the extent necessary to safeguard the public health." The qualifying language thus defines the standard by which *tolerances* are to be determined and not the occasions on which *regulations* are to be promulgated.

promulgate regulations . . . to such extent as he finds necessary," the Court ignores the import of the words immediately following, which specify the effect of the "limits *so* fixed"—*i. e.*, fixed by "limiting the quantity [of the poisonous substance] therein or thereon to such extent as he finds necessary for the protection of public health"—which can only mean that the qualification modifies the *limits* set by regulation rather than the *duty* to regulate. In addition, the Court's construction, by skipping over the words "limiting the quantity therein or thereon," renders them superfluous and of no operative force or effect. Indeed, the Court renders the very language it construes superfluous, because reading the provision to authorize (rather than mandate) the promulgation of regulations assigns it an office already filled by the general rulemaking authority conferred later in the Food, Drug, and Cosmetic Act. See 21 U. S. C. § 371(a).[2] If Congress intended the Secretary to have unbridled authority to proceed with action levels, instead of with formal regulations, there was no need to enact this part of § 346 at all. This is plainly a case in which "the intent of Congress is clear [and] the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–843 (1984).[3]

---

[2] The Court does not deny that the specific language which it construes—the clause providing that "the Secretary shall promulgate regulations" setting tolerance levels—is superfluous under its view of the Act. See *ante*, at 9. It instead emphasizes that a later sentence in § 346 which prescribes the legal *effect* of tolerance-setting regulations remains effective. But since tolerances may be promulgated pursuant to § 371(a), as well as § 346, the Court's response merely underscores the fact that its construction of the "shall promulgate" clause to authorize rather than to require such rulemaking renders it redundant to the general rulemaking authority conferred by § 371(a).

[3] Because Congress explicitly required the Commissioner to promulgate regulations for added, unavoidable contaminants, that should be "the end of the matter." *Chevron U. S. A. Inc.* v. *Natural Resources Defense*

The task of interpreting a statute requires more than merely inventing an ambiguity and invoking administrative deference. A statute is not "unclear unless we think there are decent arguments for each of two competing interpreta-

---

Council, Inc., 467 U. S., at 842. The Commissioner's "longstanding" practice to the contrary does not help his legal position. For even if it were true that the Commissioner has from time to time announced an "action level" to advise the industry when he intended to institute enforcement proceedings concerning certain deleterious substances, the fact that the FDA had never actually addressed in any detail the statutory authorization under which it took such action means that its plea for deference should fail for the reasons carefully stated in *SEC* v. *Sloan*, 436 U. S. 103, 117–118 (1978):

> "The Commission next argues that its interpretation of the statute—that the statute authorizes successive suspension orders—has been both consistent and longstanding, dating from 1944. It is thus entitled to great deference. See *United States* v. *National Assn. of Securities Dealers*, 422 U. S. 694, 710 (1975); *Saxbe* v. *Bustos*, 419 U. S. 65, 74 (1974).
>
> "While this undoubtedly is true as a general principle of law, it is not an argument of sufficient force in this case to overcome the clear contrary indications of the statute itself. In the first place it is not apparent from the record that on any of the occasions when a series of consecutive summary suspension orders was issued the Commission actually addressed in any detail the statutory authorization under which it took that action.
>
> . . . . .
>
> "[S]ince this Court can only speculate as to the Commission's reasons for reaching the conclusion that it did, the mere issuance of consecutive summary suspension orders, without a concomitant exegesis of the statutory authority for doing so, obviously lacks 'power to persuade' as to the existence of such authority. [*Adamo Wrecking Co.* v. *United States*, 434 U. S. 275, 287, n. 5 (1978).]"

As we emphasized in *FMC* v. *Seatrain Lines, Inc.*, 411 U. S. 726, 745 (1973), "an agency may not bootstrap itself into an area in which it has no jurisdiction by repeatedly violating its statutory mandate." Instead, "our clear duty in such a situation is to reject the administrative interpretation of the statute." *SEC* v. *Sloan*, 436 U. S., at 119.

The *Sloan* case also provides an adequate answer to the argument that Congress has revisited the statute from time to time without condemning the FDA's "action level" practice:

tions of it." R. Dworkin, Law's Empire 352 (1986). Thus, to say that the statute is susceptible of two meanings, as does the Court, is not to say that either is acceptable. Furthermore, to say that the Commissioner's interpretation of the statute merits deference, as does the Court, is not to say that the singularly judicial role of marking the boundaries of agency choice is at an end. As Justice Frankfurter reminds us, "[t]he purpose of construction being the ascertainment of meaning, every consideration brought to bear for the solution of that problem must be devoted to that end alone." Frankfurter, Some Reflections on the Reading of Statutes, 47 Colum. L. Rev. 527, 529 (1947). It is not "a ritual to be observed by unimaginative adherence to well-worn professional phrases." *Ibid.* "Nor can canons of construction save us from the anguish of judgment." *Id.*, at 544. The Court, correctly self-conscious of the limits of the judicial role, employs a reasoning so formulaic that it trivializes the art of judging.

I respectfully dissent.

"We are extremely hesitant to presume general congressional awareness of the Commission's construction based only upon a few isolated statements in the thousands of pages of legislative documents. That language in a Committee Report, without additional indication of more widespread congressional awareness, is simply not sufficient to invoke the presumption in a case such as this. For here its invocation would result in a construction of the statute which not only is at odds with the language of the section in question and the pattern of the statute taken as a whole, but also is extremely far reaching in terms of the virtually untrammeled and unreviewable power it would vest in a regulatory agency." *Id.*, at 121.